REMARKS

Claims 1 and 18 (and claims dependent thereon) have been revised to introduce the features of a human cell comprising a nucleic acid encoding IL-10, and a human subject. Specification support for the revision of claims 1 and 18 may be found throughout the instant application as originally filed, for example at paragraphs [0032] and [0063]. Claim 8 has been revised to use alternative language to set forth features of the claimed invention. Claim 25 has been re-written in independent form, incorporating the features of previously presented claim 18 from which it had depended.

Claims 26-33 are new. New dependent claims 26 and 28 further provide the feature that said cell is transfected or infected with a vector containing the nucleic acid encoding IL-10 *ex vivo* prior to delivering to a human subject. Specification support for new claims 26 and 28 may be found in the instant application as originally filed at least at paragraphs [0047], [0054], and [0062]. New dependent claims 27 and 29 further provide the feature of autologous cells; specification support may be found in the instant application as originally filed at least at paragraphs [0048] and [0064]. New dependent claims 30 and 31 further provide the feature of *in vitro* culturing; specification support may be found at least at paragraphs [0047] and [0062]. New dependent claims 32 and 33 further provide the feature of selecting transfected or infected cells *in vitro* prior to delivering; specification support may be found at least at paragraphs [0038] and [0061].

No new matter has been introduced; entry of the above revised (and new) claims is respectfully requested.

Previously Presented Claim 25

Applicants respectfully point out that claim 25 was pending at the time the instant Office Action was mailed (May 5, 2008) but was not examined on the merits. Claim 25 was previously presented by Applicants in the Listing of Claims accompanying their submission dated December 14, 2006, with inclusion of features of claim 18 from which it depended. Applicants believe that examination of claim 25 was inadvertently overlooked by the Office.

In the current Listing of Claims, claim 25 has been re-written in independent form to incorporate the features of previously presented claim 18 from which it had previously depended. Applicants respectfully submit that examination of claim 25 "on the merits" occur prior to the

next Office communication. Should that communication include a rejection of claim 25, it would be the first rejection of the claim.

Alleged Rejections Under 35 U.S.C. § 112 (First Paragraph)

Claims 1, 4-8, 18, and 21-24 stand rejected under 35 U.S.C. § 112 first paragraph as allegedly failing to comply with the enablement requirement. Applicants have carefully reviewed the statement of rejection as well as the cited documents and respectfully traverse the grounds for this rejection. Applicants submit that there is no *prima facie* case of non-enablement present, and that one of ordinary skill in the relevant art would know how to practice the full breadth of the claimed invention based upon the teachings provided by the instant specification and the general knowledge in the field, without undue experimentation.

Regarding the Examiner's assertion alleging that the FGS/Kist rodent model is not predictive of larger animals, including humans, Applicants point out that this animal model was obtained from the Korean Research Institute of Bioscience and Biotechnology (see, for example, at paragraph [0090] of the instant specification. Applicants further submit that this model was generally recognized by those of ordinary skill in the art to represent an acceptable model of glomerulosclerosis and proteinuria in humans, at the time the instant application was filed. See, for example, Park, Ho-Sun et al., J. Korean Med. Sci. 18:527-33, 2003; see p527, second column, lines 5-10, and references therein (a copy of this document is provided attached herewith). So, as early as 1991 the FGS/Kist rodent model was recognized as demonstrative of glomerulosclerosis and/or protienuria disease in humans. Thus, the FGS/Kist rodent model provides sufficient art recognized guidance for the practice of the instant claims in the human context and consequently no undue experimentation is needed. While this recognition in the art was not expressly indicated in the application as filed, Applicants submit that it is not necessary to specifically disclose what is generally known and accepted by those of ordinary skill in the relevant art (see, for example, MPEP at 2164.01 where it is stated that "A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984)."

Applicants point out that the relevant standard is that no undue experimentation be necessary to make and use the claimed invention. The absence of undue experimentation is not equivalent to the necessary presence of absolute predictability and/or the lack of experimentation. To the contrary, a need for routine and repetitive experimentation is wholly consistent with the presence of an enabling disclosure (see the facts of *In re Wands*). Furthermore, Applicants respectfully submit that the instant rejection is not supported by evidence regarding why the pending claims, in combination with the recognized animal model, guidance provided by the instant application, and knowledge in the art would require undue experimentation for their enablement. To the contrary, Applicants have shown, using the FGS/Kist rodent model, based upon expression of IL-10, a reduction in glomerular sclerotic index (Table 2, Example 15) as well as proteinuria (Table 3, Example 16). And because the FGS/Kist model is accepted as representative of glomerulosclerotic and proteinuria disease in humans, the skilled person would recognize that no undue experimentation is needed to provide human subjects with a similar result. So, successful use of the FGS/Kist model, as disclosed in the instant application, provides direct and relevant guidance to the skilled person for the use of the subject matter as claimed. In the absence of evidence overcoming this disclosure, no issue relating to enablement is present.

The Examiner also alleges that Tomasoni et al. reports that gene therapy for renal diseases is a long way from being reasonably predictable. However, Applicants respectfully traverse and submit that Tomasoni et al. report a number of successes, including with the use of allogenic cells (see, for example, page 118, second column, under "Ex Vivo Studies" and at page 119 under "Transplantation"). This is consistent with the instant claims which feature a method of delivering human cells to a human subject, including the use of cells treated *ex vivo*. As the Examiner acknowledges "it is difficult to argue that *ex vivo* approaches are not sufficiently enabled" (see page 5, 4th full paragraph of the Office Action mailed May 5, 2008). Consequently, Applicants submit that in light of the above arguments and revision of claims 1 and 18 (and claims dependent thereon), this rejection under 35 U.S.C. § 112 first paragraph is misplaced and may be properly withdrawn.

Conclusion

It is believed that the application is now in condition for allowance. Applicant requests the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR §§1.16 and 1.17 and to credit any overpayment to said Deposit Account No. 502486.

Respectfully submitted,

JHK Law

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